# Ethical Implications of Standardization of ICU Care with Computerized Protocols

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## ABSTRACT

*Ethical issues related to the use of computerized protocols to control mechanical ventilation of patients with Acute Respiratory Distress Syndrome (ARDS) are identical to the ethical issues surrounding the use of any therapy or intervention. Four ethical principles must be considered: nonmaleficence, beneficence, autonomy, and distributed justice. The major ethical challenges to computerized protocol use as a specific application of clinical decision support tools are found within the principles of nonmaleficence and of beneficence. The absence of credible outcome data on which ARDS patient survival probabilities with different therapeutic options could be based is a constraint common to most ICU clinical decision making. Clinicians are thus deprived of the knowledge necessary to define benefit and are limited to beneficent intention in clinical decisions. Computerized protocol controlled decision making for the clinical management of mechanical ventilation for ARDS patients is ethically defensible . It is as well supported as most ICU therapy options.*

## INTRODUCTION

A systematic overview of ethical implications of a new therapy requires consideration of four basic principles in biomedical ethics: nonmaleficence (do no harm), beneficence (do good), autonomy (respect for patient self direction), and distributive justice (be fair) [1, 2]. When the decision to treat has been made, and the only choice remaining relates to the technique or process of delivering the treatment, issues usually considered under the purvue of the principles of autonomy and distributive justice become less important. The importance of the principles of nonmaleficance and of beneficence remain undeminished. While nonmaleficence is frequently the overriding principle, the committment of the health care professions to provide benefit to patients is virtually universal [1]. Striking a reasonable balance between the principles of nonmaleficence and beneficence is a frequent challenge in serving the patient's best interest [3]. In effect, a risk-benefit assessment must be made, and is best made with sound data on which to base probability estimates of outcome for the treatment options under consideration. For patients with life-threatening hypoxic respiratory failure, the acute respiratory distress syndrome (ARDS), the outcome of interest is patient survival [4]. Unfortunately, credible outcome data are generally unavailable for many medical problems, including ARDS [5]. Only about 15% of medical interventions are supported with any scientific data [6, 7], and only 0.7% of interventions were reported to be supported by at least moderately strong scientific evidence [6]. Care must be exercised when choosing treatments without credible scientific outcome data, since potent modern interventions can induce harm as well as good. Mechanical ventilation for life-support of ARDS patients has both the potential for good (benefit) [8-10] and the potential for harm [11-16]. This paper addresses the ethical implications of using executable computerized protocols to control mechanical ventilation of patients with ARDS.

## PROTOCOL CONTROL OF CARE

Virtually all clinical trials employ protocols. These protocols include definitions, patient selection criteria, procedural rules, and guidelines for conduct of the trial. They generally provide some specific instructions, but not enough detail to adequately control the moment to moment process of care. Algorithms usually contain non-specific, judgment requiring suggstions like "optimize PEEP" or "maximize antibiotic therapy." While these are useful general statements and concepts, they are not executable instructions. Clinical algorithm texts and other published guidelines contain many such general instructions [17-21]. While general instructions are of value for their conceptual content, they fail to standardize therapy because they are conceptual in focus and require judgment by the clinician before steps in the algorithm can be carried out. The application of general guidelines is associated with variation of practice by different clinicians [22]. Finally, guidelines in general have so far failed to significantly impact the practice of medicine or its cost [5, 23, 24].

Computerized protocols eliminate unnecessary variation in clinical care [25], thus standardizing clinical care and imposing control on the clinical care process. This control can be expected to reduce noise introduced by the clinical caregiver and thereby increase the signal-to-noise ratio for ultimate clinical outcomes [26-29]. Unaided humans are not capable of providing the persistent commitment to detail and to decision making logic (rules) necessary to effect standardization of care comparable to that achieved by an executable computerized protocol. The hectic ICU environment makes it even more difficult. Since treatments must be applied in a uniform manner to comparable patients before one can evaluate the

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outcome of a particular medical intervention, this standardization of care is of importance [30].

## DEVELOPMENT & IMPLEMENTATION

Computerized protocols [26, 27, 31] were developed to control the intensity of care of patients enrolled in a randomized clinical trial in which ARDS patient outcome after extracorporeal support was compared with that after mechanical ventilation alone [9]. We reasoned that standardization of therapy would increase the interpretability and credibility of our clinical trial results. Our protocol-control goals were to ensure uniformity of care, equal intensity and frequency of monitoring, consistent decision making logic, and common therapeutic targets (e.g., PaO2).

Published protocols for respiratory management of ARDS did not provide the detail and specific instructions we were seeking[17-19, 21, 32-34]. We developed protocols for controlling continuous positive pressure ventilation, pressure controlled inverse ratio ventilation [35], low frequency positive pressure ventilation-extracorporeal CO2 removal, and continuous positive airway pressure.

The protocols were initially developed and used at the bedside in paper-based flow diagram form. After about 7,000 hours of around the clock use, the protocols were computerized using the LDS Hospital Health Evaluation through Logical Processing (HELP) information system [36, 37]. The HELP system provides bedside access, through computer terminals, to a fully integrated real time computerized patient data base for every patient. Computerized protocols automatically generated therapy instructions, 24 hours a day for the clinical care team, on each patient's bedside workstation [27, 38]. This bedside expert system controlled mechanical ventilation 95% of the time in routine around-the-clock clinical application. In 72 ARDS patients, 92% of 19,455 computerized protocol instructions were accepted and followed by the LDS Hospital clinical staff [27]. The protocols achieved the PaO2, target of 59 mm Hg in patients supported extracorporeally as well as in patients supported only with traditional mechanical ventilation [9] in spite of the dramatic differences between the two therapies. Intensity of care, for which the number of changes of FIO2 and PEEP per day were surrogates, was also almost identical in both groups of patients even though one group received prolonged extracorporeal support. Survival of ARDS patients supported with computerized protocol was four times the expected rate from historical controls [9]

These protocols are now used routinely for ARDS patients in the Shock Trauma/Intermountain Respiratory Intensive Care Unit at the LDS Hospital and have been used for over 50,000 hours in over 150 ARDS patients. The protocols have been exported to a personal computer platform and are currently being used in a clinical trial at one hospital in Los Angeles and one hospital in Houston. At these two hospitals 94% of 4,531 computerized protocol instructions in 12 ARDS patients have been accepted and followed by the clinical staffs of these two institutions (protocol performance is indistinguishable from that at the LDS Hospital).

## AUTONOMY & DISTRIBUTED JUSTICE

The principle of autonomy requires patient participation and the acquisition of informed consent for application of new or non-standard treatments [1, 2]. Two opposing arguments can be mounted regarding the need for informed consent for the use of computerized protocol control of mechanical ventilation for ARDS patients. Firstly, computerized protocol control could be viewed as new and innovative non-standard therapy with undefined risks and benefits. One could argue that since much medical decision making requires frequent knowledge domain changes, protocol control of decision making will not likely be successful. Informed consent would then be mandatory. Secondly, computerized protocol control could be viewed as a decision support tool that merely formalizes and standardizes common practice. The forethought and concensus development required for protocol generation [25, 26] leads to a more precise and detailed articulation of the explicit and implicit rules applied in standard clinical practice (albeit with variability) [22]. Decisions under protocol control would, therefore, be made with more forethought and planning than would be decisions made individually by an independent practitioner [5]. Certain iterative therapies, such as mechanical ventilation, can be considered tasks within a single knowledge domain, and thus would be amenable to computerized protocol control. In this argument protocols are viewed as an extension of the common practice of generating guidelines [5] such as critical paths, routine sets of orders, etc., all of which are efforts to standardize care. Informed consent would then not be mandatory. At the LDS Hospital, the Institutional Review Board has accepted the latter argument and we do not require that informed consent be obtained for the use of computerized protocol control of mechanical ventilation.

The principle of distributive justice raises no obstacles to the use of computerized protocol control as long as it is applied to all appropriate patients without prejudice.

## NONMALEFICENCE AND BENEFICENCE

The principles of nonmaleficence and beneficence are the source of major challenges to protocol control of care. These challenges are frequently couched in questions like "How can you be sure the protocol incorporates the right clinical care?" or "Physicians must be free to decide so the best therapy can be

chosen for each individual patient." The use of computerized protocol control challenges the traditional authority of medical experts. Protocol control might thus be viewed as a threat, rather than as a complement, to the clinical *status quo*, in light of the common belief that medical experts maximize patient benefit by individualizing decisions.

Computerized protocols for mechanical ventilation of ARDS patients actually generate decisions that are no less individualized than decisions in many other clinical care domains. Firstly, other treatments such as drug therapy for hypotension or for infections are standardized with respect to drug dose, frequency and route of administration. Secondly, the mechanical ventilation support of ARDS patients is not standardized by computerized protocols. It is the computerized protocol logical elements and the decisions that result from error signals that are standardized. The actual treatment instructed by the protocol varies from patient to patient. The input data and the computerized protocol output instructions are both patient-specific. The standardized logic of the protocol generates individualized treatment instructions in response to the individual patient's unique physiologic expression of ARDS.

Beneficence can involve both the conferring of benefit on the patient and the intent to confer benefit without such achievement. The intention to do good is sometimes persuasive in itself [1]. For the critically ill ICU patient with ARDS, for whom the decision to provide mechanical ventilation has already been made, the overriding outcome variable is patient survival. Intentions to do good or to be benevolent pale in importance with actions that achieve increases in survival. Outcome data that can lead to credible estimations of survival probabilities for different treatment options become crucial to clinical decision making, whether protocol controlled or not. Unfortunately necessary data are unavailable and many complex clinical decisions must therefore be based on the clinician's intention to do good. The intention to do good is often insufficient [29, 39-42], although laudable [1].

Many ARDS clinical trial design flaws, and many clinical objections to performing clinical trials for patients with ARDS or other life-threatening problems, are based on "ethical concerns" originating in the expert or authoritarian paradigm that has been the foundation of the traditional patient-physician relationship. The physician is the expert and posesses the requisite training, knowledge, and experience to provide the advice necesary to guide the patient towards a favorable outome. In this process, the patients "best interest" is served by provision of the "best available" therapy [43]. The physician's "belief" in the superiority of a therapeutic choice is cited as a foundation of ethical decision making [43] and of the fiduciary nature of the physician-patient encounter [3, 43]. The absence of such a belief in the face of therapeutic options constitutes the state of "equipoise" within an individual physician (individual equipoise) or within the medical community (clinical equipoise) [43, 44]. When equipoise is present, randomized clinical trials comparing therapeutic possibilities seem justified. A number of concerns can be raised in response to this traditional view. Firstly, the implicit assumption that physician belief is a reliable reflection of the best information is not responsive to general human limitations with information processing [28, 29, 35, 45, 46]. Ignoring these limitations raises physician "belief" to a level of undeserved importance. Physician "belief" in the superiority of complex therapies may, in fact, undermine the fiduciary relationship that should exist between physician and patient [3, 43] by exposing the patient to undesirable therapy.

Secondly, the "belief" of the adherents of a particular policy, in itself, provides no justification for the policy. The belief is no more than an opinion. The policy can only rationally be justified by data or arguments. Belief can be based on credible outcome data or on unfounded conjecture. Belief is commonly based on considerations that fall on a continuum between credible outcome data and unfounded conjecture. Belief insufficiently grounded in credible outcome data, even when based on extensive personal and medical community experience, can mislead well intended clinicians to make decisions that fail to benefit and even bring harm to their patients. The results of the Vineberg procedure for angina pectoris, with its 75% positive placebo effect [47], and of the Cardiac Arrhythmia Suppression Trial (CAST) with its unexpectedly high mortality associated with effective suppression of premature ventricular beats following myocardial infarction [41] are graphic examples of this danger. Other important examples are easily found and include O2 therapy for neonatal respiratory distress [40], gastric freezing for upper gastrointentinal hemorrhage, laetrile for cancer, rapid I.V. infusion of 5-FU for colorectal cancer, intrarterial infusion of chemotherapeutic agents for colorectal liver metastases, hydrocortisone after myocardial infarction [30], splenectomy for Gaucher's disease, and frontal lobotomy. It is of interest, therefore, to find belief, in itself used as a justification for some of the most consequential and onerous decisions in critical care medicine [43, 48, 49]. To be fair, it must be acknowledged that some workers demand that physician opinion be based on reliable actuarial data [39, 49, 50], but this does not appear to be a universal expectation. It is rapidly appreciated that belief itself is neither sufficient nor even always necessary for the effectuation of correct therapy. The steadfast belief of the medical adherents of Laetrile therapy did not make the therapy correct, nor could it

justify the conduct of a clinical trial [49]. Just as the individual practitioner cannot invoke idiosyncratic good intentions as a defense, so also should this avenue of defense be forbidden to the expert committee that may be charged with defining a standard of care for the medical community. Poorly supported opinion, no matter how well intended, does not gain accuracy by being offered by a dozen experts rather than by one practitioner.

The common clinical concerns raised about computerized protocol controlled care are reflections of the strength of the authoritarian paradigm and of the beliefs of the clinicians that practice within this paradigm. Open discussion of the limitations of such beliefs when bereft of supporting scientific data has been an effective means of overcoming these clinical concerns in the LDS Hospital and in the hospitals, in Los Angeles and Houston, to which the computerized mechanical ventilation protocols have been exported.

## SUMMARY

The ethical implications and challenges raised by the use of computerized protocol control of clinical decision making appear to be identical to the issues raised by therapeutic interventions in general, both in clinical practice and in clinical trials. In the absence of credible data concerning outcome (survival) probabilities for different therapy options, clinicians are forced to use intent rather than patient benefit as the operational decision driver regarding the principle of beneficence. The use of computerized protocols raises ethical questions that are qualitatively indistinguishable from those encountered routinely in clinical care. Available reports indicate that further development and evaluation of protocol control of care is clinically and ethically desirable.

## REFERENCE

1. Beauchamp T, Childress J. Principles of biomedical ethics. (3 ed.) New York: Oxford University Press, Inc, 1989:470.
2. Jonsen A, Siegler M, Winslade W. Clinical ethics. (3 ed.) New York, NY: McGraw-Hill, Inc., 1992
3. Moline J. Professionals and professions: A philosophical examination of an ideal. Soc Sci Med 1986;22(5):501-508.
4. Morris A. ARDS and new modes of mechanical ventilation: Reducing the complications of high volume and high pressure. New Horizons 1994;2(1):19-33.
5. James B, Eddy D. CPI and practice guidelines. In: Horn S, Hopkins D, ed. Clinical practice improvement: A new technology for developing cost-effective quality health care. New York: Faulker & Gray, Inc., 1994: 271. vol 1).
6. Williamson J, Goldschmidt P, Jillson I. Medical Practice Information Demonstration Project-Final Report (Contract #282-77-0068GS).Baltimore, MD: Office of the Asst. Secretary of Health, DHEW, 1979
7. White K. Foreward. In: Payer L, ed. Medicine and culture. New York, NY: Henry Holt, 1988: 9.
8. Hickling K. Low volume ventilation with permissive hypercapnia in the Adult Respiratory Distress Syndrome. Clin Intens Care 1992;3:67-78.
9. Morris A, Wallace C, Menlove R, Clemmer T, Orme JJ, Weaver L, Dean N, Thomas F, East T, Suchyta M, Beck E, Bombino M, Sittig D, Böhm S, Hoffmann B, Becks H, Pace N, Butler S, Pearl J, Rasmusson B. A randomized clinical trial of pressure-controlled inverse ratio ventilation and extracorporeal CO2 removal for ARDS. Am J Respir Crit Care Med 1994;149(2):295-305.
10. Tobin M., ed. Principles and practice of mechanical ventilation.New York, NY: McGraw-Hill, Inc., 1994.
11. Slavin G, Nunn JF, Crow J. Bronchiolectasis, A complication of artificial ventilation. Br Med J (Clin Res Ed) 1982;285(6346):931-934.
12. Albelda SM, Gefter WB, Kelley MA, Epstein DM, Miller WT. Ventilator-induced subpleural air cytsts clinical radiographic and pathologic significance. Am Rev Respir Dis 1983;127:360-365.
13. Churg A, Golden J, Fligiel S, Hogg JC. Bronchopulmonary displasia in the adult. Am Rev Respir Dis 1983;127:117-120.
14. Tsuno K, Prato P, Kolobow T. Acute lung injury from mechanical ventilation at moderately high airway pressures. J Appl Physiol 1990;69(3):956-961.
15. Dreyfuss D, Saumon G. Lung overinflation: Physiologic and anatomic alterations leading to pulmonary edema. In: Zapol WM, LeMaire F, ed. Adult respiratory distress syndrome. New York: Marcel Dekker, Inc., 1991: 433-449. (Lenfant C, ed. Lung biology in health and disease; vol 50).
16. Dreyfuss D, Saumon G. Role of tidal volume, FRC, and end-inspiratory volume in the development of pulmonary edema following mechanical ventilation. Am Rev Respir Dis 1993;148:1194-1203.
17. Boutros AR, Hoyt JL, Boyd WC, Harford CE. Algorithm for management of pulmonary complications in burn patients. Crit Care Med 1977;5(2):89.
18. Don H, ed. Decision making in critical care. Philadelphia, St Louis: BC Decker Inc., The CV Mosby Company, 1985:Clinical decision making Series
19. Karlinsky J, Lau J, Goldstein R. Decision making in pulmonary medicine.Philadelphia: BC Decker, 1991
20. Armstrong R, Bullen C, Cohen S, Singer M, Webb A. Critical care algorithms.New York, NY: Oxford University Press, 1991:100.

21. Guidelines-Committee-Society-of-Critical-Care-Medicine. Guidelines for the care of patients with hemodynamic instability associated with sepsis. Crit Care Med 1992;20(7):1057-1059.
22. James B, Horn S, Stephenson R. Management by fact: What is CPI and how is it used? In: Horn S, Hopkins D, ed. Clinical practice improvement: A new technology for developing cost-effective quality health care. New York: Faulker & Gray, Inc., 1994: 39-54. vol 1).
23. Anderson C. Measuring what works in health care. Science 1994;263:1080-1083.
24. Walker R, Howard M, Lambert M, R S. Medical practice guidelines. West J Med 1994;161(1):39-44.
25. Morris A, James B. CPI and computerized protocols. In: Horn S, Hopkins D, ed. Clinical practice improvement: A new technology for developing cost-effective quality health care. New York: Faulker & Gray, Inc., 1994: 271. vol 1).
26. East T, Morris A, Wallace C, Clemmer T, Orme JJ, Weaver L, Henderson S, Sittig D. A strategy for development of computerized critical care decision support systems. Int J Clin Monit Comput 1992;8:263-269.
27. Henderson S, Crapo R, Wallace C, East T, Morris A, Gardner R. Performance of computerized protocols for the management of arterial oxygenation in an intensive care unit. Int J Clin Monit Comput 1992;8:271-280.
28. Morris A, Gardner R. Computer applications. In: Hall J, Schmidt G, Wood L, ed. Principles of Critical Care. New York: McGraw-Hill, 1992: 500-514.
29. Morris A. Paradigms in management. In: Pinsky M, Dhainaut J, ed. Pathophysiologic foundations of critical care medicine. Baltimore: Williams and Wilkens, 1993: 193-206.
30. Pocock SJ. Clinical Trials: A Practical Approach.New York, NY: John Wiley & Sons, 1983:266.
31. East T, Morris A, Gardner R. Computerized management of mechanical ventilation. In: Grenvik A, Ayres S, ed. Textbook of critical care. 3 ed. Philadelphia, PA: W. B. Saunders Company, In Press:
32. NHLI. Protocol for extracorporeal support for respiratory insufficiency collaborative program.Bethesda: National Heart and Lung Institute, Division of Lung Diseases, 1974
33. Shoemaker WC. A patient care algorithm for cardiac arrest. Crit Care Med 1978;4:157.
34. Bryan-Brown C, Shapiro B, Miller C, Kathirithamby K. A less invasive approach to monitoring acute respiratory failure. Med Instrum 1979;13(6):327-329.
35. East TD, Böhm SH, Wallace CJ, Clemmer TP, Weaver LK, Orme JF Jr, Morris AH. A successful computerized protocol for clinical management of pressure control inverse ratio ventilation in ARDS patients. Chest 1992;101:697-710.
36. Pryor TA, Warner HR, Gardner RM, Clayton PD, Haug PJ. The HELP system development tools. In: Orthner H, Blum B, ed. Implementing health care information systems. New York: Springer-Verlag, 1989: 365-383.
37. Kuperman GJ, Garder RM, Pryor TA. HELP: A Dynamic Hospital Information System.New York: Springer-Verlag, 1991(Orthner HF, ed. Computers and Medicine
38. Henderson S, Crapo RO, East TD, Morris AH, Gardner RM. Computerized clinical protocols in an intensive care unit; How well are they followed? In: Miller RA, ed. Fourteenth Annual Symposium on Computer Applications in Medical Care. Washington, DC: IEEE Computer Soc Press, 1990: 284-288.
39. Chalmers T. A belated randomized controlled trial. Pediatrics 1990;85(3):366-369.
40. Silverman W. Human experimentation: A guided step into the unknown.Oxford, England: Oxford University Press, 1985
41. The Cardiac Arrhythmia Suppression Trial II Investigators. Effect of the antiarrhythmic agent moricizine on survival after myocardial infarction. N Engl J Med 1992;327(4):227-233.
42. Silverman W. Doing more good than harm. Ann NY Acad Sci 1993;703:5-11.
43. Truog R. Randomized clinical trials: Lessons from ECMO. Clin Res 1992;40(3):519-527.
44. Meinert C. Extracorporeal membrane oxygenation trials. Pediatrics 1990;85(3):365-366.
45. Miller G. The magical number seven, plus or minus two: Some limits on our capacity for processing information. Psychol Rev 1956;63(2):81-97.
46. Miller J. Living systems.New York: McGraw-Hill Book Company, 1978
47. Hulley S, Cummings S. Designing Clinical Research.Baltimore: Williams and Wilkins, 1988
48. O'Rourke P, Crone R. Pediatric applications of extracorporeal membrane oxygenation (Editorial). J Pediatr 1990;116:393-394.
49. Levine R. Ethics and regulation of clinical research. (2 ed.) New Haven: Yale University Press, 1988
50. Chalmers I. Minimizing harm and maximizing benefit during innovation in health care: Controlled or uncontrolled experimentation? BIRTH 1986;13(3):155-164.

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